UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ORTHO-McNEIL
PHARMACEUTICAL INC.,

Plaintiff,

Case No. 04-CV-73698

vs.

HON. GEORGE CARAM STEEH

CARACO PHARMACEUTICAL
LABORATORIES, LTD.,

Defendant.
_____/

OPINION AND ORDER GRANTING DEFENDANT'S
MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT

FACTUAL BACKGROUND

Ortho-McNeil is a pharmaceutical company headquartered in Illinois. In 1994, Ortho obtained a patent, U.S. Patent No. 5,336,691 or "'691 Patent", to combine two well-known pain-relieving drugs, namely tramadol and acetaminophen, into a tablet form known as Ultracet. When Ortho initially applied to the PTO for this patent, a similar patent, more commonly known as the "Flick" patent was in existence. The Flick patent discussed the synergistic qualities of tramadol when combined with other pain-relieving drugs, and contained a dialogue about the combination of tramadol and acetaminophen in a ratio of 1 to 10, or 1:10. Ortho disclaimed Flick as prior art, stating that it "does not disclose a composition comprising a tramadol material and acetaminophen in the claimed weight ratios much less any weight ratios." In 2004, Ortho initiated a Reissue Proceeding whereby it sought to distinguish its invention from Flick. Ortho reissued its

patent application, guarantying to manufacture a combination of the two drugs in a ratio of "about 1:5", which they purported to the PTO was materially different from the prior art ratio of 1:10. The PTO rejected Claim 6 of the '691 Patent as being clearly anticipated by Flick. This rejection on May 10, 2005 is not a final ruling, so the '691 Patent is still valid.

Presently, Ortho is attempting to prevent Caraco from manufacturing a generic form of Ortho's drug Ultracet. Ortho filed this patent infringement suit under the Hatch-Waxman Act, which requires the FDA to stay approval of ANDAs for 30 months while the ANDA filer and NDA/patent holder litigate the patent issues. 21 U.S.C. § 355(c)(3). Caraco's ANDA states that it plans to produce this drug with a ratio of 1:8.67. Initially, Caraco conceded that their drug would have a manufacturing variance as low as 1:6.4. In order to enter the market earlier and avoid a protracted dispute with Ortho, Caraco recently amended its ANDA to cut its authorized manufacturing variability in half to a minimum of 1:7.5.

Caraco is requesting that this court grant summary judgment in its favor and dismiss Ortho's claims against it with prejudice. Oral argument was held before the Court on October 7, 2005. For the reasons described below, Caraco's motion is GRANTED.

STANDARD FOR SUMMARY JUDGMENT

Federal Rule of Civil Procedure 56(c) empowers the court to render summary judgment "forthwith if the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a

matter of law." See Redding v. St. Eward, 241 F.3d 530, 532 (6th Cir. 2001). The Supreme Court has affirmed the court's use of summary judgment as an integral part of the fair and efficient administration of justice. The procedure is not a disfavored procedural shortcut. Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986); see also Cox v. Kentucky Dept. of Transp., 53 F.3d 146, 149 (6th Cir. 1995).

The standard for determining whether summary judgment is appropriate is "'whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.'" Amway Distributors Benefits Ass'n v. Northfield Ins. Co., 323 F.3d 386, 390 (6th Cir. 2003) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251-52 (1986)). The evidence and all reasonable inferences must be construed in the light most favorable to the non-moving party. Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Redding, 241 F.3d at 532 (6th Cir. 2001). "[T]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986) (emphasis in original); see also National Satellite Sports, Inc. v. Eliadis, Inc., 253 F.3d 900, 907 (6th Cir. 2001).

If the movant establishes by use of the material specified in Rule 56(c) that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law, the opposing party must come forward with "specific facts showing that there is a genuine issue for trial." First Nat'l Bank v. Cities Serv. Co., 391 U.S. 253, 270 (1968); see also McLean v. 988011 Ontario, Ltd., 224 F.3d 797, 800 (6th Cir. 2000). Mere

allegations or denials in the non-movant's pleadings will not meet this burden, nor will a mere scintilla of evidence supporting the non-moving party. Anderson, 477 U.S. at 248, 252. Rather, there must be evidence on which a jury could reasonably find for the non-movant. McLean, 224 F.3d at 800 (citing Anderson, 477 U.S. at 252).

ANALYSIS

I. Construction of Claim 6

Claim 6 includes four limitations: (1) "pharmaceutical composition"; (2) "a tramadol material"; (3) "acetaminophen"; and (4) a "weight ratio of the tramadol material to acetaminophen" of "about 1:5." Caraco does not contest the first three limitations of Claim 6, therefore the fourth limitation is the only issue for purposes of summary judgment.

To interpret a claim limitation, the Court uses the perspective of "a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). The claims are of primary importance, and "the words of a claim are generally given their ordinary and customary meaning." Id. at 1312. The specification is the best guide to the meaning of a disputed term, though extrinsic evidence in the form of expert testimony can be useful to provide background on the technology at issue or to establish that a term has a particular meaning in the pertinent field. Id. at 1315, 1318.

The term "about" is commonly used in patent claims to broaden numerical limitations and must be construed in the light of the specific facts of each case. E.g., Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995) ("The use of

the word 'about,' avoids a strict numerical boundary to the specified parameter."). The term "about" is defined as meaning "approximately" in the Oxford English Dictionary, and this meaning has also been used in some cases by the Federal Circuit Court. See, Merck & Co. v. Teva Pharma. USA, Inc., 395 F.3d 1364, 1369-70 (Fed. Cir. 2005).

Ortho's position is that a person of skill in the art would evaluate the animal testing data in the patent to ascertain the degree of variability associated with the term "about". Table 1 and Figure 1 of the '691 patent display ED50 values that show the amount of a combined dose of tramadol and acetaminophen needed to provide pain relief in 50% of the test subjects (i.e., mice). Ortho's experts read Table 1 and Figure 1 to reveal that combinations containing between 3.3 and 4.7 mg/kg of tramadol and between 16.7 and 23.4 mg/kg of acetaminophen (i.e., ratios of 1:3.6 to 1:7.1) are statistically indistinguishable from the tested combination at a ratio of 1:5 in yielding pain relief in 50% of the test subjects. According to Ortho's experts, one of ordinary skill in the art would conclude that "about 1:5" includes a range of ratios that "extends up to and includes 1:7.1." This opinion is given by Donald R. Stanski, M.D. and is confirmed by Eric Smith, Ph.D. (Stanski Inf. Rep., p. 2, p. 7, ¶ 12; Smith Inf. Rep. p. 25). These ranges are termed 95% confidence levels, indicating the range within which the tested ED50 value would fall 95% of the time if the mouse tests were repeated. Therefore, Ortho concludes that the scope of the limitation "about 1:5" necessarily extends somewhat beyond the range described.

Each of the claims of the '691 Patent that claim a weight ratio use the term "about" preceding the ratio. While many of these ratios are stated as ranges, Claim 6 is not. Obviously the drafters of the patent were able to state weight ratios as ranges

when they wanted to. Furthermore, the repeated use of the term "about" indicates contemplation of minor measuring errors. This conclusion is further supported by the fact that the phrase "about 1:5" describes weight ratios and nowhere specifies confidence level ratios or statistically equivalent ratios.

In patent infringement litigation taking place in New Jersey, Ortho has contended that a weight ratio of about 1:5 constitutes a ratio range of "at least" 1:3.6 to 1:7.1. The words "at least" preceding a range of numbers defining the term "about 1:5" results in a meaningless and boundless construction. Such a construction would clearly run into the prior art because the Flick patent's 1:10 ratio is "at least" 1:7.1. In addition, Ortho's expert Dr. Stanski stated that a person skilled in the art would interpret the ratio of "about 1:5" to include compositions where the ratio "extends up to and includes 1:7.1." (Stanski Infringement Rep. at ¶ 12). "Up to" 1:7.1 would put an upper limit on the range, while "at least" 1:3.6 to 1:7.1 has no upper limit.

The Federal Circuit opines that expert testimony, which is "generated at the time of and for the purpose of litigation," is "less reliable" than the patent itself in defining claim terms. Phillips, 415 F.3d at 1318. Expert testimony should be rejected when it "is clearly at odds with the claim construction mandated by the claims themselves . . . ." Id. Claim 6 refers to a "weight ratio of about 1:5", yet Dr. Stanski argues that defining "about 1:5" requires a statistical comparison of the pharmacological effect of various drug ratios in mice. First, Claim 6 does not refer to dosage combinations with "about" the same pharmacological profile as a weight ratio of 1:5. Second, nothing in the patent's specification suggests that defining "about 1:5" requires a statistical analysis of data concerning analgesic effect in mice. The patent repeatedly uses the term "about"

to refer to weight measurements. ('691 Patent, col. 5, ll. 5-11) (referring to "dosage[s]" of "about 800mg/kg," "about .3 to 200 mg/kg," and "about 10 to 6000 mg/kg/day"). Third, the patent distinguishes between weight ratios as close as 1:5 and 1:5.7 (id. at Figure 1), which contradicts Dr. Stanski's opinion that all ratios between 1:3.6 to 1:7.1 are the same as 1:5.

Taking into consideration all of the arguments contained in the parties' briefs, the Court construes the term "about 1:5" in Claim 6 to mean a weight ratio of approximately 1:5, encompassing a range of ratios of no greater than 1:3.6 to 1:7.1.

II. Literal Infringement

While Caraco's original ANDA literally infringes Claim 6, it is the amended ANDA, which narrows the uniformity standards and contains the additional requirement that the weight ratio for each tablet must be at least 1:7.5, that controls. The Stipulation entered by the parties says that Caraco's ANDA "as filed and as subsequently modified from time to time during FDA review, is the only relevant document for strict purposes of infringement in this litigation." Contrary to Ortho's argument, it is the amended ANDA application that the Court should rely on under the parties' Stipulation.

Caraco's amended ANDA specification requires that each tablet have no greater than a 7.5% deviation from the stated product description of 37.5 mg tramadol and 325 mg acetaminophen, which encompasses a range of ratios from 1:7.46 to 1:10.07. Caraco's amended ANDA further expressly forbids it from manufacturing a single tablet with a ratio below 1:7.5, which does not overlap with the upper limit of Ortho's 1:7.1 weight ratio. Therefore, Ortho cannot establish literal infringement as a matter of law.

III. Doctrine of Equivalents

The doctrine of equivalents allows the patentee "to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes" to the literal scope of the claims. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722, 733 (2002). A product may conceivably infringe under the doctrine of equivalents, even though it does not literally infringe, if it "performs substantially the same overall function or work, in substantially the same way, to produce substantially the same overall result as the claimed invention." Dolly, Inc. v. Spalding & Evenflo Companies, Inc., 16 F.3d 394, 397 (Fed. Cir. 1994). "[T]he doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997).

To address concerns that "the doctrine of equivalents has taken on a life of its own," courts have developed "an array of legal limitations, formulations, and tests regarding the doctrine of equivalents." K-2 Corp. v. Salomon, 191 F.3d 1356, 1366 (Fed. Cir. 1999). "These limitations on the doctrine of equivalents are questions of law." K-2 Corp., 191 F.3d at 1367.

A. The Doctrine May Not Remove the Ratio Limitation from the Claim

The Supreme Court has explained, "[i]t is important to ensure that the application of the doctrine [of equivalents], even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety." Warner-Jenkinson, 520 U.S. at 29. Courts must exercise a "special vigilance against allowing the concept of equivalence to eliminate completely any [claim] elements." Id. at 40.

The Federal Circuit reaffirmed this principle recently in Freedman Seating Co. v. American Seating Co., 420 F.3d 1350 (Fed. Cir. 2005). The patentee in that case manufactured seats used in public transportation vehicles, which have the ability to fold away in order to create more interior space for passengers with wheelchairs. The patent claimed a stowable seat with a "slidably mounted" seat base, while the accused seat base was "rotatably mounted." The patentee argued that the two seat bases had the same function-way-result because both allowed "the moveable end of the support member . . . translational and rotational motion relative to the seatbase." Id. at 1362. In reversing the district court's finding of infringement under the doctrine of equivalents, the court stated:

> [T]aken to its logical conclusion, Freedman's argument would mean that any support member capable of allowing translational and rotational motion would be equivalent to a support member "slidably mounted to said seatbase," which reads "slidably mounted" completely out of the claims. This is the precise type of overextension of the doctrine of equivalents that the claim vitiation doctrine is intended to prevent.

Id.

Ortho's theory is that 1:5 and 1:8.67 are equivalent because, as Dr. Stanski opined, the claimed and accused pharmaceutical compositions "have the same function," operate "the same way" and "will yield an insubstantially different result," thus satisfying all three prongs of the function/way/result test for equivalence. According to Dr. Stanski, the function of both ratios is to create analgesia; each "would confer their analgesic effect in the same way" by producing "synergistic analgesic effects"; and each would have the same result because they will "yield analgesia with a smaller amount of

Tramadol and APAP" due to synergistic analgesic effects. (Stanski Inf. Rpt., p. 13, ¶ 31-33).

The '691 Patent specification provides that "compositions having a ratio of tramadol to APAP from 1:1 to 1:1600" exhibit enhanced synergistic analgesic effects. Therefore, Ortho's theory of equivalence would cover all ratios from 1:1 to 1:1600. However, an upper boundary of the "about 1:5" ratio must be recognized or it would be permitted to extend to the prior art of 1:10 and beyond. There is no basis to say that the ratio of "about 1:5" is equivalent to a ratio of 1:8.67, but not to 1:10. The theory that the "doctrine of equivalents cannot allow a patent to encompass subject matter existing in the prior art", argued by Ortho, is a separate limitation on the application of the doctrine of equivalents. K-2 Corp., 191 F.3d at 1367 (citing Wilson Sporting Goods Co. v. David Geoffrey & Assoc., 904 F.2d 677, 684 (Fed. Cir. 1990)). Such limitation on the doctrine cannot be used affirmatively by Ortho to have an equitable upper limit placed on the ratio in Claim 6.

Ortho's theory would render the "about 1:5" ratio meaningless and read it out of Claim 6. The doctrine of equivalents does not permit this result, and therefore does not apply to this case.

B. Other Limitations on Doctrine of Equivalents

Caraco argues two other limitations on the doctrine of equivalents in this case: the theory encompasses the prior art; and the theory improperly expands an intentionally narrow claim. Having found that the theory eviscerates a claim element, it is not necessary for the Court to address Caraco's further limitation arguments.

CONCLUSION

For the reasons stated in this opinion and order, Caraco's motion for summary judgment of non-infringement is GRANTED.

s/George Caram Steeh
GEORGE CARAM STEEH
UNITED STATES DISTRICT JUDGE

Dated: October 19, 2005

CERTIFICATE OF SERVICE

Copies of this Order were served on the attorneys of record on October 19, 2005, by electronic and/or ordinary mail.

s/Josephine Chaffee
Secretary/Deputy Clerk